

**REMARKS/ARGUMENTS**

**I. Status of the claims**

Claims 1 and 16-18 are amended and claim 15 is canceled. Claims 1, 4-5, 7-13, and 16-26 are pending with entry of the Amendment. Claims 16-17 and claims 22-23 were withdrawn from consideration by the Examiner. Applicants thank the Examiner for withdrawing the indefiniteness and various prior art rejections. Applicants also thank the Examiner for the recent helpful interview.

**II. Support for the Amendments**

Support for the amendments can be found throughout the specification and originally-filed claims. The amendments to claim 1 merely incorporate the limitations of previously pending claims 15 and 25-26. The amendments to claims 16-18 merely change dependency. No new matter is added.

**III. Withdrawn claims**

The Office Action withdrew claims 16-17 and 22-23 from consideration because there was allegedly no allowable linking claim. Applicants submit, as discussed below, that submitted claim 1 is allowable and is a generic linking claims for claims 16-17 and 22-23. Therefore, Applicants respectfully request inclusion of the claims in the examination and ultimately in the granted patent.

**IV. Rejection under 35 USC § 112, first paragraph: enablement**

Claims 1, 4-5, 7-13, 15, 18-21, 25, and 26 were rejected for alleged lack of enablement under 35 USC § 112, first paragraph. The rejection indicated that the claimed subject matter was enabled where the expressed protein is expressed in the cell wall and wherein the protein was 2D-CD4, but argued that broader scope was not enabled. Applicants respectfully traverse the rejection.

It is Applicants understanding in view of the interview that with entry of the above amendments the claims are allowable. The amendments clarify two issues. First, the amendments indicate that the expressed protein is expressed in the cell wall or is released from the bacterium. These aspects are described, for example, in paragraph 65 of the present specification. As explained for example in paragraph 67, the cell wall targeting regions (such as set forth in claim 1) direct fused proteins to the bacterial cell wall. If a charged region of amino acids is also included at or near the carboxyl terminus of the protein, the protein will generally remain anchored in the cell wall. If the charged region is not present, the protein will generally be released from the bacterium. Both cell wall anchored and released proteins are thus fully enabled by the specification.

With regard to the biologically active protein expressed, Applicants submit that in view of the present specification one of ordinary skill in the art would have been able to express essentially all biologically active proteins in bacteria as of the filing date. The specification provides information regarding transformation of *L. jensenii* and also describes expression of active polypeptide. It should be noted that the USPTO has already acknowledged that one can generally express biologically active proteins in *L. jensenii*. See, e.g., US Patent No. 7,312,076. Finally, those of skill in the art have expressed a huge number of biologically active proteins in bacteria over the past forty years. In view of the successes demonstrated in the present specification, there is not reason to doubt that there would be particular difficulty in expressing most proteins while retaining activity in view of the information provided in the specification.

In view of the arguments above, Applicants respectfully request withdrawal of the rejection.

**V.      *Obviousness-type double patenting rejections***

**A.      *Rejection over US Patent No. 7,312,076***

Claims 1, 4-5, 7-13, 15, 18-21, 25 and 26 were rejected for alleged obviousness-type double patenting over claims 1-12 of US Patent No. 7,312,076. According to the Office Action, the present claims and those of the '076 are not identical but are not patentably distinct. Applicants submit that the claims are patentably distinct.

Whereas the claims of the '076 patent are directed to any *Lactobacillus jensenii* bacterium recombinantly altered to express a biologically active protein, the present claim is directed to a non-obvious subset of *L. jensenii* that express a biologically active protein linked to a particular heterologous cell wall targeting sequence. It is Applicants' position that the art did not teach or suggest the recited heterologous cell wall targeting sequences. The cell wall targeting sequences in the present claims were not disclosed in other references, nor are they presented in the claims of the '076 patent. While the Office Action notes that some cell wall anchoring sequences are disclosed in the specification of the '076 patent, Applicants note that the MPEP specifically states: "When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art." *See*, MPEP § 804(II)(B)(1) (emphasis added). Moreover, Applicants note that the priority application of the '076 did not describe the specific anchoring sequences relied upon in the Office Action and thus the disclosure in the initial priority application (US Provisional Patent Application No 60/443,619) of the present application is earlier than the first disclosure in the '076 patent family.

In view of the above arguments, the claims of the '076 patent cannot render the claims of the present application obvious. Withdrawal of the rejection is respectfully requested.

**B. Rejection over US Patent No. 7,456,011**

Claims 1, 4-5, 7-13, 15, 18-21, 25 and 26 were rejected for alleged obviousness-type double patenting over claims 1-2 of US Patent No. 7,456,011. According to the Office Action, the present claims and those of the '011 are not identical but are not patentably distinct. Applicants submit that the claims are patentably distinct.

Whereas the claims of the '011 patent are directed to a *Lactobacillus* bacterium that expressed a modified cyanovirin-N protein, the present claim is directed to a *L. jensenii* that express a biologically active protein linked to a particular heterologous cell wall targeting sequence. Thus, the claims of the '011 do not teach or suggest a cell wall targeting sequence and the present claims do not teach or suggest the modified cyanovirin-N recited in the '011 claims. Thus, it is unclear why the present claims would be considered obvious over the '011 patent

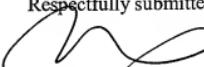
claims and vice versa. The Office Action provides no explanation why one of ordinary skill in the art would have found these differences obvious. Accordingly, the claims of the '011 patent cannot render the claims of the present application obvious. Withdrawal of the rejection is respectfully requested.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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